

WHAT IS CLAIMED IS:

1 1. A method for remodeling luminal tissue, said method comprising:
2 positioning a vibrational transducer at a target site in a body lumen of a
3 patient; and
4 energizing the vibrational transducer to produce acoustic energy under
5 conditions selected to induce tissue remodeling in at least a portion of the tissue
6 circumferentially surrounding the body lumen.

1 2. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least shrink the tissue.

1 3. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which reduces the compliance of the tissue in either or both the radial and
3 longitudinal directions.

1 4. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least induce collagen formation in the tissue.

1 5. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least cause cavitation in the tissue.

1 6. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least interrupt nerve pathways in the tissue.

1 7. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least interrupt the reception and/or production of biochemicals in the
3 tissue.

1 8. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least interrupt the ability of the tissue to absorb food.

1 9. A method as in claim 1, wherein the acoustic energy is produced under
2 conditions which at least selectively destroy intestinal metaplasia in the esophagus.

1 10. A method as in claim 1, wherein the transducer is energized to produce
2 acoustic energy in the range from 10 W/cm² to 100 W/cm².

- 1 11. A method as in claim 1, wherein the transducer is energized at a duty
2 cycle from 10 % to 100 %.
- 1 12. A method as in claim 1, wherein the transducer is energized under
2 conditions which heat the tissue to a temperature in the range from 55°C to 95°C.
- 1 13. A method as in claim 1, further comprising cooling the luminal surface
2 tissue while tissue beneath the surface is heated.
- 1 14. A method as in claim 1, wherein positioning the vibrational transducer
2 comprises introducing a catheter which carries the transducer into the body lumen.
- 1 15. A method as in claim 14, wherein positioning further comprises
2 inflating a balloon in the catheter to at least partly engage the luminal wall and locate the
3 transducer at a pre-determined position relative to the target site.
- 1 16. A method as in claim 15, wherein the transducer is inside the balloon
2 and inflating the balloon with an acoustically transmissive material which centers the
3 transducer within the lumen and enhances transmission of the acoustic energy to the tissue.
- 1 17. A method as in claim 15, wherein the transducer is located between a
2 pair of axially spaced-apart balloons and inflating the balloon centers the transducer within
3 the lumen, further comprising introducing an acoustically transmissive medium between the
4 balloons to enhance transmission of the acoustic energy to the tissue.
- 1 18. A method as in claim 15, further comprising moving the transducer
2 relative to the balloon(s) in order to focus or scan the acoustic energy axially on the luminal
3 tissue surface.
- 1 19. A method as in claim 16, wherein the acoustically transmissive
2 medium is cooled to cool the luminal tissue surface.
- 1 20. A method as in claim 1, further comprising monitoring temperature at
2 the luminal tissue surface.
- 1 21. A method as in claim 1, further comprising monitoring temperature
2 below the luminal tissue surface.

1 22. A method as in claim 1, wherein energizing comprises focusing the
2 acoustic energy beneath the luminal tissue surface.

1 23. A method as in claim 1, wherein energizing comprises focusing the
2 acoustic energy at or just before the luminal tissue surface.

3 24. A method as in claim 27, wherein the vibrational transducer comprised
4 a phased array.

1 25. A method as in claim 24, wherein the phased array is selectively
2 energized to focus the acoustic energy at one or more desired locations in the tissue
3 surrounding the body lumen.

1 26. A method as in claim 1, wherein positioning the vibrational transducer
2 comprises:
3 introducing a cannula to the target site;
4 expanding a balloon on the cannula at the target site with an acoustically
5 transmissive medium; and
6 selectively directing the vibrational transducer within the balloon to remodel
7 targeted tissue.

1 27. A method as in claim 26, further comprising viewing the target tissue
2 through a scope in or on the cannula while directing the vibrational transducer.

1 28. A method as in claim 26, wherein selectively directing comprises
2 deflecting and/or rotating a beam transducer.

1 29. A method as in claim 26, wherein selectively directing comprises
2 axially translating a circumferential array transducer.

1 30. A method as in claim 26, wherein selectively directing comprises
2 everting the transducer to direct energy against tissue surrounding an opening to the body
3 lumen.

1 31. A method as in claim 30, wherein the balloon is expanded over the
2 entire opening.

1 32. A method as in claim 31, wherein the balloon is expanded over a
2 location adjacent to the opening.

1 33. A method as in claim 26, wherein selectively directing comprises
2 pivoting at least one transducer from a fixed location within the balloon.

1 34. A method as in claim 33, further comprising deflecting at least one
2 additional transducer from a fixed location within the balloon.

1 35. A method as in claim 26, wherein selectively directing comprises
2 expanding a second balloon disposed over the vibrational transducer, wherein the second
3 balloon may be axially translated within the first balloon.

1 36. A method as in claim 1, wherein positioning the vibrational transducer
2 comprises: expanding a balloon over an opening at one end of the body lumen;
3 filling the end of the lumen over the balloon with an acoustically transmissive
4 medium; and
5 positioning the vibrational transducer within the medium to direct acoustic
6 energy at the luminal tissue.

1 37. A method as in claim 1, wherein positioning the transducer comprises:
2 capturing luminal tissue between opposed elements, wherein the transducer is
3 disposed on one of the elements; and
4 directing energy from the transducer into the captured tissue.

1 38. A method as in claim 37, wherein capturing comprises clamping with
2 movable elements.

1 39. A method as in claim 37, wherein capturing comprises applying a
2 vacuum to the tissue to draw said tissue between the opposed elements.

1 40. A method as in claim 1, wherein the body lumen is the esophagus and
2 the patient suffers from gastroesophageal reflux disease (GERD).

1 41. A method as in claim 40, wherein the acoustic energy remodels the
2 tissue surrounding a lower esophageal sphincter.

1 42. A method as in claim 1, wherein the body lumen is the stomach and
2 the patient suffers from a hiatal hernia.

1 43. A method as in claim 42, wherein the acoustic energy remodels the
2 tissue surrounding a diaphragmatic sphincter.

1 44. Apparatus for remodeling the lower esophageal sphincter, said
2 apparatus comprising:
3 a catheter adapted to be esophageally introduced to the lower esophageal
4 sphincter (LES); and
5 a vibrational transducer on the catheter adapted to deliver acoustic energy to
6 the tissue of the LES in order to lessen gastroesophageal reflux.

1 45. Apparatus as in claim 44, further comprising an inflatable balloon on
2 the catheter, wherein said balloon is adapted when inflated to position the catheter within the
3 LES so that the transducer can deliver energy to the LES.

1 46. Apparatus as in claim 45 wherein the transducer is positioned coaxially
2 with the balloon.

1 47. Apparatus as in claim 45, further comprising means for inflating the
2 balloon with an acoustically transmissive medium.

1 48. Apparatus as in claim 45 wherein the transducer is positioned between
2 a pair of spaced-apart balloons.

1 49. Apparatus as in claim 44, further comprising means for delivering an
2 acoustically transmissive medium between the balloons.

1 50. Apparatus as in claim 44, further comprising means for cooling the
2 acoustically transmissive medium.

1 51. Apparatus as in claim 44, further comprising means for measuring
2 temperature at or beneath the luminal wall.

1 52. Apparatus as in claim 44, further comprising means to axially translate
2 the transducer relative to the catheter.

1 53. Apparatus as in claim 44, wherein the transducer comprises a phased
2 array.

1 54. A system comprising:
2 apparatus as in claim 44; and
3 a cannula having a channel for receiving and deploying the catheter.

1 55. A system as in claim 54, further comprising a viewing scope which is
2 part of or introducable through the cannula.

1 56. A system as in claim 54, wherein the cannula further comprises an
2 inflatable balloon over a distal end, wherein the catheter is extendible from the cannula into
3 the balloon when the balloon is inflated.

1 57. A system as in claim 56, wherein the vibrational transducer on the
2 catheter is deflectable and/or rotatable and/or evertable within the balloon when inflated.

1 58. A system as in claim 56, wherein the vibrational transducer on the
2 catheter comprises a circumferential array and is axially translatable within the balloon when
3 inflated.

1 59. A system as in claim 56, wherein the transducer is pivotally mounted
2 on the catheter.

1 60. A system as in claim 56, wherein the transducer is mounted on at least
2 one of a pair of spaced-apart elements on the catheter configured to receive target tissue
3 therebetween.

1 61. A system as in claim 60, wherein the spaced-apart elements are
2 movable to clamp tissue therebetween.

1 62. A system as in claim 60, wherein a vacuum source is disposed on the
2 catheter to selectively draw tissue into the space between the spaced-apart elements.